Cases found under a search of "medical Food" and (FTC or FDA).

There only appears to be one reported case in the search engine that I used that really addresses the concept of a medical food: U.S. v. Ten Cartons, Ener-B Nasal Gel, 888 F. Supp. 381 (E.D.N.Y., 1995). Because the defendant is referred to repeatedly as Nature's Bounty, this paper will refer to it as the Nature's Bounty case. The facts involved a nasally administered vitamin B-12 preparation; the principal issue turned on whether that could be considered a medical food.

The District Court succinctly describes the case based on the magistrate's report:

"Before the Court are the objections of the defendant Nature's Bounty, Inc. ("Nature's Bounty" or "defendant") to the Report and Recommendation of United States Magistrate Judge Allyne R. Ross — now a United States District Judge in this district — dated September 23, 1994 ("Report"), regarding the defendant's nasally administered vitamin B-12 preparation called Ener-B Nasal Gel ("Ener-B"). This Court referred to Judge Ross the issue of whether Ener-B is a "food" or a "drug" within the meaning given to these terms by the Federal Food, Drug and Cosmetic Act ("FDCA" or the "Act"), 21 U.S.C. §§ 301-395 (1988 & Supp. V 1993) (unless otherwise indicated, all citations to the U.S.C. are to the 1988 edition and 1993 volume supplement). Judge Ross found that the Food and Drug Administration ("FDA") reasonably determined that Ener-B was a drug and not a "food" within the meaning of sections 201(f) and 201(g)(1)(C) of the Act, 21 U.S.C. §§ 321(f) and 321(g)(1)(C), and recommended that the Court defer to the agency's determination. Her well-reasoned and thorough Report merits publication and is appended at the end of this opinion.

BACKGROUND

The defendant markets Ener-B, which is intended to be applied to the inside of one's nose. As intended to be used, the vitamin B-12 contained in Ener-B bypasses digestion through the gastrointestinal tract, where it would be absorbed into the body through the intestines. Instead, Ener-B's vitamin B-12 is absorbed directly into the blood stream through the nasal mucosa.

On February 26, 1987, the FDA notified Nature's Bounty that the FDA considered Ener-B to be a "drug" under the FDCA, and that Ener-B was being marketed illegally because it had not received recognition or approval as a "new drug" under the Act. The FDA also alleged that Ener-B was misbranded and improperly labelled under the Act. The FDA's notice informed Nature's Bounty that the Act provided for the seizure of illegal products, and for an injunction against the distributor of such products."

Id. at 384-385.

The Plaintiff had moved for summary judgment on the grounds that the product was a medical food within the meaning of FDC Act section. The Court denied summary judgment in 1991 by Memorandum Decision and Order reported at 1991 WL 641573, 1991 U.S.Dist. LEXIS 14872 (E.D.N.Y.1991)

After evidentiary hearings in 1993:

"Judge Ross found that the credible expert testimony offered at the hearing, by both the Government's and the defendant's experts, strongly supported the conclusion that the common

sense and scientific definitions of "food" entail two elements: (i) nutrient intake, and (ii) ingestion into the gastrointestinal tract of such nutrients, also known as enteral administration of nutrients. According to Judge Ross, ingestion into the gastrointestinal tract was viewed as a necessary element of a food by the medical and scientific communities:

> The common sense and scientific definitions of "food ... for man" that incorporate as a necessary element ingestion into the gastrointestinal tract are both reasonable and accepted by a substantial segment of the medical and scientific community. As evidenced by certain defense expert definitions, other respectable segments of the scientific community apparently adopt a more expansive definition that includes parenterally administered nutrients as well. This showing, however, does not impeach the evidence that a definition requiring enteral administration is reasonable and is also well accepted by credible scientists.
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> [Magistrate's] Report at 9-10."

Id.

In an extremely long opinion, the District Court rejected a variety of arguments. Arguments dealing with an allegedly changed litigation position by the FDA, and arbitrariness and capriciousness as to the determination that food could include nasal administration were rejected and will not be discussed.

As the date of 1995 indicates, the case involved facts and law prior to the 1994 Diet Supplement Amendments.

The Court had this to say about the amendments:

> "After Nature's Bounty filed its Objections, Congress enacted the Dietary Supplement Health and Education Act of 1994, Pub.L. No. 103-417, 1994 U.S.C.C.A.N. (108 Stat.) 4325 (codified at various sections of 21 U.S.C. § 301-395 and 42 U.S.C. §§ 281(b)(2) and 287c-3) (enacted on October 25, 1994, hereinafter "DSHEA"). The DSHEA, among other things, amends the FDCA by providing that subject to certain exceptions, products defined as "dietary supplements," which include vitamins, minerals, amino acids and herbs, are a "food" and are not to be classified as a "drug" under section 321(g)(1) solely because of any statements on the products' labelling regarding claims to alleviating a nutritional deficiency or disease. See DSHEA §§ 3, 10 (defining a "dietary supplement" and amending 21 U.S.C. § 321(g)(1); respectively codified at 21 U.S.C.A. §§ 321(ff) and 321(g)(1) (West Supp.1994)). Significantly, the DSHEA also amends section 350(c)(1)(B) by adding the words "powder, softgel, and gelcap" after "capsule" in section 350(c)(1)(B)(i). See DSHEA § 3(c) (codified at 21 U.S.C.A. § 350(c)(1)(B)(i) (West Supp.1994))."

The Court characterized the Nature's bounty argument as follows:

> "Nature's Bounty contends that the DSHEA substantially affects the posture of this case, because the DSHEA has established a new class of products called "dietary supplements" which are defined as foods and are allegedly excluded from regulation as a drug under section

> 321(g)(1)(C). According to the defendant, all of the testimony and evidence presented by the Government before Judge Ross to support its contention that Ener-B is not a food is "now moot." Indeed, the defendant contends that the debate over the "food" exemption under section 321(g)(1)(C) is "totally irrelevant" in light of the DSHEA, and that the Court should disregard Judge Ross's Report as well as the parties' objections and response papers. Instead, Nature's Bounty claims that the Court should focus on whether Ener-B is exempt from regulation as a "drug," because it is a "dietary supplement" under the DSHEA that is subject to an entirely new statutory-regulatory framework."

Id. at 389-90.

As the opinion continued, the Court held:

> "In order to be excluded from regulation as a "drug" under the provisions of sections 350(a) and (b) — in other words, in order to be a "food to which this section 350 applies" —, a product must, under the definition of that phrase in section 350(c) prior to the DSHEA amendments, be a "food for humans which is a food for special dietary use" which (A) is a vitamin or mineral, and (B) "which is (i) intended for ingestion in tablet, capsule, or liquid form, or (ii) if not intended for ingestion in such a form, does not simulate and is not represented as conventional food ... or for use as a sole item of a meal or of a diet."
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> As explained earlier, Nature's Bounty contends that Ener-B meets the definition of a "food to which section 350 applies," because Ener-B is a food for special dietary use which is a vitamin, and which, according to the defendant, is "not intended for ingestion" within the meaning of section 350(c)(1)(B)(ii).
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> While the defendant is correct to assert that Ener-B may be used for a "special dietary use" as that term is defined in section 350(c)(3)(B), namely "to supply a vitamin for use by man to supplement his or her diet," the defendant's contention that Ener-B is subject to the protection of section 350 ultimately fails, because the remaining requirements that are necessary for Ener-B to be a "food" to which section 350 applies are not met. Specifically, under section 350(c)(1)(B) Ener-B must be "intended for ingestion" either in a tablet, capsule or liquid form, or if not in that form, than it must be "intended for ingestion" in some other form. Ener-B however, is not intended for "ingestion" as that term is meant to be used in the statute. The defendant's construction of section 350(c)(1)(B)(ii) to apply to foods for special dietary use that are "not intended for ingestion" is erroneous, because it reads out of the statute the words "in such form."

Id. at 392-393.

In sum, the two key takeaways were that the Court would defer to the agency interpretation, and the words "intended for ingestion" meant exactly that.

Subsequently, in 1995, the Orphan Drug Amendments were enacted. This was the final block of the statutory framework of medical food.

The Nutrition Labeling and Education Act of 1990 (see 21 U.S.C. 343(q)(5)(A)(iv)) had references to medical food, but excluded them from normal labeling requirements.

The statute presently reads,

> The term "medical food" means a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.

21 U.S.C. § 360ee(b)(3).

The FDA has issued several versions of Guidance regarding medical food, including as late as May, 2016. One of the most informative is "Draft Guidance for Industry: Frequently Asked Questions About Medical Foods; Second Edition [Contains Nonbinding Recommendations Draft-Not for Implementation] May 1997; May 2007; Revised August 2013.

The agency's present position is that a medical food must meet five requirements:

> "The following criteria that clarify the statutory definition of a medical food can be found in FDA's regulations at 21 CFR 101.9(j)(8). A food is a medical food and is exempt from the nutrition labeling requirements of 21 CFR 101.9 only if:
> a. It is a specially formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of a patient by means of oral intake or enteral feeding by tube.[4]
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> b. It is intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone;
> c. It provides nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation;
> d. It is intended to be used under medical supervision; and
> e. It is intended only for a patient receiving active and ongoing medical supervision wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the medical food."

FAQ at 2.

Consistent with the Nature's Bounty opinion, the FAQ makes clear in footnote 4 that "Enteral feeding by tube refers to a tube or catheter that delivers nutrients beyond the oral cavity directly into the stomach or small intestine. It should not be confused with parenteral (or intravenous) nutrient formulations which are regulated by FDA as drugs."

In terms of case law and FDA Guidance, this is where things stand today.

One case with some interesting commentary on medical food is Midlothian Laboratories, L.L.C. v. Pamlab, L.L.C., 509 F.Supp.2d 1065, 2007 WL 2458409 (M.D. Ala., 2007). This case is actually a trademark case, but because the dispute centered on a dose change of the trademarked product, the Court give its opinion on certain aspects of what is a medical food:

> "Although Foltx is marketed as a prescription product, it is not a drug. Rather, it is classified as a `medical food': a product prescribed by physicians to patients who have special nutrient needs in order to manage a disease or health condition. The U.S. Food and Drug Administration (FDA) has formulated no specific requirements for the safety or appropriate use of medical foods. "Medical foods do not have to include nutrition information on their labels, and their claims do not need to meet specific standards." U.S. Food & Drug Admin., Medical Foods, http://www.cfsan. fda.gov/dms/ds-medfd.html.
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> The Orphan Drug Amendments of 1988 enacted, for the first time, a statutory definition of "medical food":
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> "The term `medical food' means a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation."
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> Orphan Drug Amendments of 1988 § 5(b)(3), 21 U.S.C. § 360ee(3). However, the legislative history of the amendments is silent as to the types of products meant to be covered. The statutory definition was incorporated into the Federal Food, Drug and Cosmetic Act (FDCA), which exempts medical foods from the nutrition labeling, health claim, and nutrient-content-claim requirements applicable to most other foods. 21 U.S.C. § 343(q)(5)(A)(iv). The paradoxical result of this exemption is that "medical foods intended for use by sick people are subject to much less scrutiny than virtually all other foods, which are intended for the healthy general population." Regulation of Medical Foods, 61 Fed.Reg. 60,661 (proposed Nov. 29, 1996) (to be codified at 21 C.F.R. ch. I)."

509 F. Supp. 3d at 1072-73.

Other cases found in the search:

There are other cases that appeared in the search, but the holdings tend to be focused on "drug claims" or false advertising issues rather than on whether a particular product was a medical food.

Fed. Trade Comm'n v. Wellness Support Network, Inc. , Case No. 10-cv-04879-JCS, Slip Op., Feb. 19, 2014 (N.D. Cal., 2014) (an FTC deceptive practice and false advertising case; Court cited claim of : "Diabetes Breakthrough" that will "[l]ower your blood sugar, safely and effectively with absolutely NO SIDE EFFECTS!! GUARANTEED!!"), as having been made, material and unsupported by scientific evidence and therefore misleading; summary judgment for FTC; the Court rejected the argument that the FDA's

medical food guidance might be preemptive of the FTC claims). An earlier opinion in the case disqualified an expert on the FTC's motion October 4, 2013, as well as granting injunctive relief in favor of the FTC on October 4, 2013. Another opinion dealt with motions to dismiss and discussed the company's principals' involvement and potential liability as to deceptive acts (April 4, 2011).

Health Sci. Funding LLC v. U.S. Food & Drug Admin., Case No. 15-5635 (CCC-MF), Slip. Op. May 31, 2016 (D.N.J., 2016) (Plaintiff filed a declaratory judgment action for determination that product was a medical food and to enjoin the FDA from taking action against Plaintiff; case dismissed grounds of ripeness, lack of present harm and agency deferral; Court did note that diet supplements are not automatically marketable as a medical food).

Pamlab, LLC v. Seton Pharms. LLC, Case No. 10 Civ. 7680 (KMW), Slip Op. Dec. 6, 2010 (S.D.N.Y., 2010) (Medical food is only mentioned in passing and was immaterial to this false advertising case in which a preliminary injunction was denied).